

K970987

510(k) Summary
Fusion Medical Technologies, Inc.
Ball Tip Electrode

MAY - 5 1997

1. Sponsor: Fusion Medical Technologies, Inc.
1615 Plymouth Street
Mountain View, CA 94043

Contact Person: Debera Brown
Vice President, Regulatory and Clinical Affairs
2. Device Name:

Trade Name: To Be Determined
Common/Usual Name: Electrosurgical Electrode
Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories
3. Identification of the Predicate or Legally Marketed Devices to Which Equivalence is being Claimed:

Electrosurgical Electrode by Premier Dental Products
4. Device Description:

The Fusion Ball Tip Electrode is a reusable electrode for use in monopolar electrosurgical accessories.
5. Intended Use:

Intended for use by practitioners in a manner identical to similar electrosurgical electrodes of this type presently in commercial distribution. It is intended to provide electrocautery over a large surface.

6. A Statement of How the Technological Characteristics of the Device Compare to Those of the Predicate or Legally Marketed Device.

Parameter	Fusion Ball Tip Electrode	Premier Dental Electrode K923332
Indications for Use	Intended for use by practitioners in a manner identical to similar electrosurgical electrodes of this type presently in commercial distribution. It is intended to provide electrocautery over a large surface.	Intended for use by practitioners in a manner identical to similar electrosurgical electrodes of this type presently in commercial distribution. It is intended for cutting and coagulation of tissue.
Use Profile	Provided Sterile; reusable after cleaning and autoclave sterilization	Provided non-sterile; first use and reuse after autoclave or ETO sterilization
Compatibility	Standard 3/32 inch (2.4 mm) shaft fits most electrosurgery chucks and pencils	44 different configurations provided, all standard 3/32 shaft to fit most electrosurgery chucks and pencils
Material Composition	Stainless Steel shank, Polyphenylsulfone for insulation, 99% Pure Silver as electrode tip	Stainless Steel shank, Korvex 4X Teflon TFE heat shrinkable tubing, Type 304 stainless steel electrode tip
Sterilization	Provided sterile by gamma irradiation for first use	Provided non-sterile, must be sterilized by user before first use
Biocompatibility	Materials used in other medical devices; ISO 10993-1	Materials used in other devices